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10/525,726	11/25/2005	Heinz Von Der Kammer	37998-237386	3700

26694 7590 04/23/2007  
VENABLE LLP  
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EXAMINER
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CHERNYSHEV, OLGA N

ART UNIT	PAPER NUMBER
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1649

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
31 DAYS	04/23/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.



## **DETAILED ACTION**

### ***Claim Objections***

1. Claim 14 is objected as being of indefinite scope. Specifically, claim 14 is drawn to a method of claim 5 while claim 5 is limited to an assay.

### ***Election/Restrictions***

2. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1, 9, 12 and 18, in so far as they are drawn to a method of diagnosis by determining the level or activity of a protein.

Group II, claim(s) 1 and 12, in so far as they are drawn to a method of diagnosis by determining the level of activity of a polynucleotide.

Group III, claim(s) 2 and 13, in so far as they are drawn to a kit comprising protein products.

Group IV, claim(s) 2 and 13, in so far as they are drawn to a kit comprising polynucleotide products.

Group V, claim(s) 3, drawn to a modulator.

Group VI, claim(s) 4, drawn to a transgenic animal.

Group VII, claim(s) 5, in so far as it is drawn to an assay to measure the activity or level of a polypeptide.

Group VIII, claim(s) 5, in so far as it is drawn to an assay to measure the activity or level of a polynucleotide.

Group IX, claim(s) 6, 7 and 15, drawn to a method of screening for a modulator.

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Group X, claim(s) 8, 16 and 17, drawn to an assay for testing compounds.

Group XI, claim(s) 10 and 19, drawn to a method of screening for a reagent for prevention of a neurodegenerative disease.

Group XII, claim(s) 11, drawn to a method for detecting a pathological state.

3. The inventions listed as Groups I to XII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Pursuant to 37 C.F.R. § 1.475 (a), Unity of invention before the International Searching Authority, an international and a national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention"). Where a group of inventions is claimed in an application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art. As such, pursuant to 37 C.F.R. § 1.475 (b), the ISA/US considers that when an international or a national stage application containing claims to different categories of invention unity of invention exists if the claims are drawn only to one of the following combinations of categories:

- (1) A product and a process specially adapted for the manufacture of said product; or
- (2) A product and process of use of said product; or
- (3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or

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(4) A process and an apparatus or means specifically designed for carrying out the said process;  
or

(5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process.

See also 37 C.F.R. § 1.475 (e)

The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim.

4. Accordingly, the main invention (Group I) comprises the first recited method of determining a level and/or activity of a foap-13 protein. Pursuant to 37 C.F.R. § 1.475 (d), the ISA/US considers that any feature which is the subsequently recited products and methods share with the main invention does not constitute a special technical feature within the meaning of PCT Rule 13.2 and that each of such products and methods accordingly defines a separate invention. As such, each of the methods and products recited in claims 1-13 and 15-19 represent independent and distinct invention.

5. Groups II-IV and VII are directed to different assays and methods that recite structurally and functionally distinct elements, are not required one for the other, achieve different goals, and therefore constitute patentably distinct inventions. The instant specification does not disclose that these assays and methods would be used together. The methods of Groups II-IV and VII are all unrelated as they comprise distinct steps and utilize different products which demonstrates that each method has a different mode of operation. Each invention performs this function using

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structurally and functionally divergent material. For these reasons the Inventions II-IV and VII are patentably distinct.

6. Groups V and VI are independent and distinct, each from each other, because they encompass unrelated chemical compounds and transgenic animals, each of which have independent utility that is distinct for each invention which cannot be exchanged. The instant specification does not disclose of using these inventions together or any common structure/function relationship between these two inventions.

7. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

8. The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

9. Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

10. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the


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application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (571) 272-0870. The examiner can normally be reached on 8:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet L. Andres can be reached on (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Olga N. Chernyshev, Ph.D.  
Primary Examiner  
Art Unit 1649

April 18, 2007